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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,527	12/05/2001	Michael G. Bramucci	CL1709 US NA	7153

23906 7590 08/26/2003

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

14

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/007,527

Applicant(s)

BRAMUCCI ET AL.

Examiner

Konstantina Katcheves

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-- Th MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/24/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,17,20,22-25 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,17,20,22-25 and 34-38 is/are rejected.
- 7) ☒ Claim(s) 20,22,25 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1, 2, 5, 17, 20, 22-25 and 34-38 are pending in the present application.

Claims 3, 4, 6-16, 18, 19, 21, 26-33 and 39-41 have been cancelled. This Office action is in response to Paper No. 13, filed on 24 July 2003.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1, 2, 5, 17, 20, 22-25 and 34-38, in Paper No. 13 is acknowledged.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 37 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 20, 22, 25 and 34 are objected to because they depend upon cancelled claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 5, 17, 20, 22-25 and 34-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The present claims are drawn to isolated nucleic acids comprising nucleic acids encoding the replication protein, rep, as set forth in SEQ ID NO:2, nucleic acids that hybridize to the nucleic acid and sequences complementary thereto. The claims are also drawn to an isolated nucleic acid that encodes a protein of at least 379 amino acids and has 70% identity to SEQ ID NO:2 or the complements thereof.

The present claims are drawn to a very broad genus of nucleic acids for which Applicant has failed to provide an adequate written description. Nucleic acids that hybridize to SEQ ID NO:2 under the claimed conditions may not encode the rep protein

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with replication activity as disclosed in the specification. Selective nucleic acid hybridization, however, does not guarantee that those nucleic acids will encode polypeptides that retain specific replication epitopes. Thus, no structure function relationship is taught regarding sequences which hybridize to the nucleic acid sequence of SEQ ID NO:2 and epitopes that are specific for the replication function of the rep protein of SEQ ID NO:2. Applicant's claims are also drawn to nucleic acids which are complementary to SEQ ID NO:2 or sequences which hybridize to SEQ ID NO:2. As discussed above, Applicant has not taught which regions of SEQ ID NO:2 relate to the function of the encoded rep protein. Therefore, no structure-function relationship has been taught such that one of skill in the art would reasonably conclude that Applicant was in possession of the claimed genus.

Applicant's claims are also drawn to isolated nucleic acid that encodes a protein of at least 379 amino acids and has 70% identity to SEQ ID NO:2 or the complements thereof. The instant claims are drawn to sequences with undefined modifications, which encode proteins with desired activities, specifically replication activity. These are genus claims that encompass a wide array of molecules and variants. The specification does not disclose these variants or modifications, nor does it provide any teachings as to how the structures of these sequences relate to their function. Thus, the specification does not describe the complete structure of a representative number of species of the claimed invention. The specification also fails to describe a representative number of species in terms of partial structure and relevant identifying characteristics to provide guidance as to the structure-function relationship of these molecules. Thus, the specification does not describe the claimed recombinant DNA molecules in such full, clear, concise and exact

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terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
August 20, 2003


JAMES KETTER
PRIMARY EXAMINER